

REMARKS

Claims 1-7, 9-11 and 14-21 are pending in the application. Applicants have added new claims 22-32.

Applicants have deleted the phrase "solvate or *in vivo* hydrolysable ester" from claims 1-7, 9-11, 14-16, and 19. Applicants have also amended claim 2 to be consistent with the definition of R² recited in claim 1. Finally, new claims 22-32 include the subject matter deleted from claim 7.

No new subject matter has been introduced by way of these amendments. The foregoing amendments are being made for the sole purpose of expediting prosecution of the present application, and Applicants expressly reserve the right to pursue the cancelled subject matter in a later filed continuing application.

Claims 1-7, 9-11, and 14-32 will therefore be pending upon entry of the proposed amendments.

Rejections under 35 U.S.C. § 112

I. Claims 1-7, 9-11, 14-21 are rejected under 35 U.S.C. § 112, second paragraph, for allegedly failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. According to the Office (Office Action, page 2-3):

[T]he definition of various substituents groups on pyrimidine include such groups, namely esters, carbamates, alkoxycarbonyl etc. which are also *in vivo* hydrolysable and therefore it is not clear what is the difference between these variable groups and the "*in vivo* hydrolysable ester" groups. The use of ester group(s), carbamates, etc. as substituents as well as in *In vivo* hydrolysable ester as Markush choice, results in ambiguity.

Applicants respectfully disagree with the grounds for the rejection; however, to expedite the prosecution, Applicants have deleted the phrase "*in vivo* hydrolysable ester" from claims 1-7, 9-11, 14-16, and 19. In view of the foregoing, Applicants respectfully request reconsideration and withdrawal of the rejection.

II. Claims 1-7, 9-11, 14-21 are rejected for allegedly failing to comply with the enablement requirement of 35 U.S.C. § 112, first paragraph. The rejection states, in part (Office Action, page 4):

[T]he specification, while being enabling for making salts of the claimed compounds, does not reasonably provide enablement for making in-vivo hydrolysable of the claimed compounds. The claim(s) contains subject matter that was not described in the specification in such a way as to enable one skilled in the art of medicinal chemistry – to use the invention.

Applicants respectfully disagree with the grounds for the rejection; however, to expedite the prosecution, Applicants have deleted the phrase “*in vivo* hydrolysable ester” from claims 1-7, 9-11, 14-16, and 19. In view of the foregoing, Applicants respectfully request reconsideration and withdrawal of the rejection.

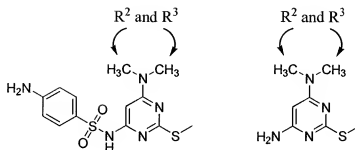
III. Claims 1-7, 9-11, 14-21 are rejected for allegedly failing to comply with the enablement requirement of 35 U.S.C. § 112, first paragraph. According to the Office (Office Action, page 6):

[T]he specification, while being enabling for making pharmaceutically acceptable salts does not reasonably provide enablement for making solvate. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Applicants respectfully disagree with the grounds for the rejection; however, to expedite the prosecution, Applicants have deleted the term “solvate” from claims 1-7, 9-11, 14-16, and 19. In view of the foregoing, Applicants respectfully request reconsideration and withdrawal of the rejection.

Rejections under 35 U.S.C. § 102

Claims 1-7, 9-11, 14-21 are rejected under 35 U.S.C. § 102(b) as being anticipated by GB 1042295 (the ‘295 patent). The Office relies on the disclosure of the “two compounds shown in example 20” (Office Action, page 10) of the ‘295 patent. For the convenience of the Office, the chemical structures of the “two compounds of example 20” are provided below.



The chemical structures shown above (referred to herein as “the example 20 compounds”) were generated from the systematic names disclosed in Example 20, page 9, lines 26-29 (2-methylthio-6-dimethylamino-4-sulfanilamido-pyrimidine and 2-methylthio-6-dimethylamino-4-aminopyrimidine) of the ‘295 patent using the ChemDraw Ultra 11.0 “convert name to structure” tool.

As can be seen, the substituents corresponding to Applicants’ R^2 and R^3 in the example 20 compounds are both unsubstituted alkyl groups, namely CH_3 . In contrast, the present claims require that when R^2 is C_{1-8} alkyl, the R^2 or R^3 alkyl group must be substituted by 1, 2 or 3 substituents independently selected from hydroxy, amino, C_{1-6} alkoxy, C_{1-6} alkylamino, di(C_{1-6} alkyl)amino, N -(C_{1-6} alkyl)- N -(phenyl)amino, N - C_{1-6} alkylcarbamoyl, N,N -di(C_{1-6} alkyl)carbamoyl, N -(C_{1-6} alkyl)- N -(phenyl)carbamoyl, carboxy, phenoxycarbonyl, $-NR^8COR^9$, $-SO_2R^{10}$, $-SO_2NR^5R^6$ and $-NR^8SO_2R^9$. As such, the example 20 compounds fall outside the scope of the present claims because the substituents corresponding to Applicants’ R_2 and R_3 in the example 20 compounds are both unsubstituted alkyl groups (i.e. CH_3) and not substituted alkyl groups as required by the present claims. Therefore, the ‘295 patent does not anticipate the present claims because the ‘295 patent does not disclose a compound meeting all of the limitations of the present claims. In view of the foregoing, Applicants respectfully request that the rejection be reconsidered and withdrawn.

CONCLUSION

Applicants submit that all claims are in condition for allowance.

The fee in the amount of \$1,050 for the three month extension fee is being paid concurrently herewith on the Electronic Filing System (EFS) by way of a Deposit Account authorization. Please apply any other charges or credits to deposit account 06-1050, referencing Attorney Docket No. 06275-436US1.

Respectfully submitted,

Date: March 24, 2008

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